



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
College Park, MD 20740

APR - 2 2003

Mr. Jim Chao
Manager
Confidence, Inc.
150-28 Union Turnpike
Suite 250
Fresh Meadows, New York 11367

Dear Mr. Chao:

This is in response to your letter of December 6, 2002 to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)) and 21 CFR 101.93(a).

21 CFR 101.93(a)(3) requires that the notice submitted pursuant to 21 U.S.C. 343(r)(6) and this section be signed by a responsible individual who can certify the accuracy of the information presented and contained in the notice, and that the individual certify that the information contained in the notice is complete and accurate, and that the notifying firm has substantiation that the statement is truthful and not misleading. Your submission does not meet this requirement in that the notice does not contain the signature of a responsible individual and, therefore, does not certify that the firm is in compliance with the requirements of the Act and the regulation. Therefore, your firm has not complied with the notification requirement in 21 U.S.C. 343(r)(6) and must submit a notification in accordance with the requirements in 21 CFR 101.93(a).

Please contact us if we may be of further assistance.

Sincerely yours,

for Robert Moore
Susan J. Walker, M.D.
Acting Director

Division of Dietary Supplement Programs
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition

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Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300

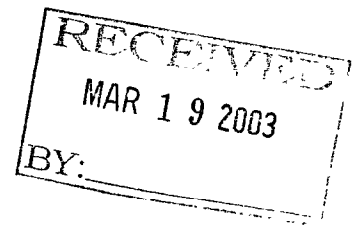
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of
Enforcement, HFC-200

FDA, New York District Office, Office of Compliance, HFR-NE140

Better Products For Better Life

December 06, 2002

Office of Special Nutritionals (HFS-450)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C Street, S. W.
Washington, DC 20204



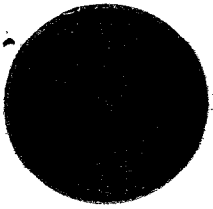
Re: Notification for Statement on Dietary Supplement 403(r)(6)

Dear Sir/Madam:

In compliance with the Dietary Supplement Health and Education Act of 1994, Confidence Inc. hereby notifies FDA that it has begun using the following statements on its product named Fe-Mon-9:

- Fe-Mon-9, as a Dietary Supplement, is formulated for Hormone Replacement Therapy in a natural way.
- Fe-Mon-9 contains the well-researched herbs Red Clover, Black Cohosh and Dong Quai that help regulate hormonal balance in women during the transitional period of menopause. This herb combination considered as an alternative medicine for HRT is strongly recommended by NIH as a treatment for PMS, as well as hot flashes and other menopausal symptoms.
- Red Clover contains phytoestrogens similar to those found in soy. The isoflavones in Red Clover such as formononetin, biochanin A daidzein and genistein are present and have been found to exert estrogen-like activities.
- Black Cohosh contains compounds that appear to act on the hypothalamus and vasomotor centers of brain, areas to help regulate body functions such as temperature control, sleep patterns and a sense of emotional well being. Complex chemicals in black Cohosh are believed to suppress the secretion of luteinizing hormone, which fluctuates during menopause.
- Dong Quai is traditionally used with other herbs as a uterine tonic.
- Fe-Mon-9 has been formulated to daily provide the active ingredients Red Clover 200 mg, Black Cohosh 100 mg, Dong Quai Root powder 100 mg, Damiana Leaf powder 100 mg, Gamma Oryzanol 100 mg, L-Arginine 100 mg, L-lysine 100 mg, DHEA 10 mg, and Pregnenolone 10 mg in amounts based on independent clinical studies and published research.
- Nutritional support for hormonal balance during menopause. Ease the transition to menopause.

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Better Products For Better Life

- Scientific studies suggest that along with a healthy diet and lifestyle, consuming phytoestrogens from Red Clover, Black Cohosh, Dong Quai may compensate for some of the reduced production of hormones during menopause. Phytoestrogens occur in significant amounts in those plants are remarkably similar in molecular structure to the female hormone estrogen and helping regulate the normal hormone fluctuation and relief the symptoms during menopause.

I herby certify that the information present and contained in this notice is complete and accurate, and my files contain substantiation that the statements made are truthful and not misleading.

Thank you for your time and attention to this matter. If you have any questions, please do not hesitate to contact the undersigned.

Very truly yours,
Confidence Inc.

Jim Chao
Manager

Attachment A: Black Cohosh
Attachment B: Red Clover
Attachment C: Dong Quai
Attachment D: Women's Health